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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm.1061
Rockville, MD 20852

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Docket No. 2005D-0330

Comments:
Guidance for Industry: Draft Guidance for Industry and FDA Review Staff on Collection of Platelets by Automated Methods

Pg. 2 "Therefore, in addition to the pH requirement as defined in 21 CFR 640.25 (b)(2), you should include additional criteria at the time of process validation and quality control (QC) testing for Platelets, Pheresis to include evaluation of pH at 6.2."
- Please clarify what is meant by "to include evaluation of pH at 6.2".

Pg.3 "Each month four units prepared from different donors be tested at the end of the storage period for the platelet count, pH …."
- Minimum of 4 units per month or is 10% of units collected required?

Pg. 5
"Donor weight of at least 110 pounds"
- What is the intent of this requirement if an automated collection machine allows for a donor's weight to be <110 pounds? It will cause a 1% decrease in our platelet collections.

Prior to first donation a WBC Count must be reviewed.
- What are the parameters for accepting a donor?
- If manufacturer has not determined a parameter, do we really need this count?

Donors who have ingested drugs.
- Why is the deferral time for aspirin 5 days rather than 36 hours?
- A list of NSAIDS is needed. This deferral time will cause a 30-50% decrease in our platelet collections.
- What are the clinical data showing the effects of NSAIDS?

Pg. 6 "You should collect no more than 24 total Platelet, Pheresis components in a 12-month period."
- What is the rationale for only allowing the collection of 24 total pheresis products?
- We believe that this will cause a 30-40% reduction in our total collections, if this requirement remains.

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"The interval between each collection of Platelets, Pheresis should be at least two (2) days with no more than two procedures in a 7-day period."

- What data or rationale are there to justify these intervals?

"A post-donation platelet count should be performed after each collection."

- Why do this, if the instrument is validated to ensure that the donor's platelet count will not be compromised with the collection procedure?
- If the count is too low, what actions should be taken?

Pg. 7 – C. Dedicated Donations

- Does this apply only to "licensed" facilities?

"...must certify in writing that the donor's health permits the collection Platelet, Pheresis."

- Request to be more specific about the acceptable parameters of the donor's health in order to be a dedicated donor.

Pg. 8 "In addition, the phlebotomy must be performed by a single uninterrupted venipuncture with minimal damage to, and minimal manipulation of, the donor's tissue."

- Does this mean that no second sticks will be allowed (using the sterile docking device)?

Pg. 8 - VI. Process Validation

- Does the agency expect the facility to perform retrospective validation on the devices used in the collection process as listed in the document?

Pg. 11 "You should use the following collection performance qualification criteria:"

- Is the facility expected to perform this performance qualification retrospectively, if not previously performed using this criteria?

Pg. 12

- If a platelet product is positive on the initial culture but negative on the re-culture, does this cause the validation to be stopped and restarted?

Table 1. Collection Performance Qualification Criteria

- Actual Platelet Yield: Minimum: 3.0×10^{11} 95%
  - Facility believes that changing the criteria from 90% to 95% will decrease our collections by about 1%.

Pg. 13 – E. Re-Qualification/Re-Validation

- Facility requests that this entire section be clarified with more concrete examples of triggers for re-qualification/re-validation.

Pg. 14 - Residual WBC counts:

- Please clarify this requirement.

Pg. 14 – RBC loss: "...you should calculate the volume of RBCs remaining in the pheresis collection set after a collection of Platelets, Pheresis and record it in the donor's record."

- Does this mean when the RBCs cannot be returned and/or a routine collection and rinse back is complete?

Sincerely,

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